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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,012	09/14/2001	Colin Gerald Caro	BKY2-0074	7764

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EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,012

Applicant(s)

CARO ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 5, 6, 12-16, 24-31 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) 28-31, 43 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 5, 6, 12-16, 24-27, 42, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Claims 28-31, 43 and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 1, 2003.

Claims 28-31 are not drawn to the elected species of Figures 6a to 6c but appear to be drawn to the species of Figure 1a, 1c, and 7-12; these claims have been withdrawn at this point in order to reduce the number of issues for prosecution.

Claim 46 was presented in the most recent response dated August 2, 2005. Upon review of the specification for original support, it was determined that it is drawn to non-elected species A (Figures 1a and 1c); see the paragraph bridging pages 6 and 7 of the specification.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 6, 24-27, 42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by MacGregor (US 5,015,253) as evidenced by Prince (US 5,579,767), and as further evidenced by McGuinness (US 6,156,062), Khosravi et al (US 6,425,915) and Hogan (US 6,569,191). MacGregor anticipates the claim language where it is applied to and in the shape of an aneurysm and an aneurysm is known to produce swirl flow as evidenced by Prince; see Figure 2, column 1, lines 25-55 and column 6, lines 26-43 of MacGregor and see column 2, lines 26-36 of Prince. For this reason, the claim language, pertaining to swirl flow, is considered fully inherently met. The shape and/or orientation of the stent is considered to be non-planar because it is a cylinder. Cylinders are considered to be non-planar curves, to the extent this language can be given patentable weight, because a cylinder is a curved three-dimensional shape where no area of its surface is in the same plane.

McGuinness (see column 5, lines 53-63), Khosravi (see column 9, lines 47-60), and Hogan (see Figures 8D and 8E as well as column 5, lines 23-30) all provide evidence that stents with helical projections or surfaces embed themselves into the surface of the vessel upon application. For this reason, the Examiner asserts that the stent of MacGregor would also become embedded in the stent wall upon expansion and make an impression thereof on the interior of the stent. Since the stent of MacGregor is at least partially helical, it would inherently impart this at least partially helical shape to the interior of the blood vessel.

Regarding claim 26, Applicants are directed to column 2, lines 21-31, column 4, lines 6-19, and column 6, lines 26-43 where the expanded shape is retained or

remembered to the extent that the language "shape memory alloy" can be given patentable weight.

Claims 42 is rejected under 35 U.S.C. 102(b) as anticipated by Caro (WO 95/09585). Caro anticipates the claim language where the stent with supporting part as claimed is met by the shaped vascular prosthesis that includes "a stent or other structural support of plastic, metal or other material"; see the abstract and page 5, line 28 to page 6, line 10. This shaped tube of Caro especially with a metal stent therein would inherently impose a shape on a vessel it is inserted into because it is designed to be rigid enough to prevent kinking or collapse. The tube of Figure 5 or at least that of Figures 7 and 8 can be inserted into a vein or artery and would presumably not collapse or kink therein because that would make it inoperable; see page 6, lines 24-30. The stent of Caro can be outside the tube such that it "internally supports" the blood vessel it is inserted into.

Claims 12-16 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacGregor as applied to claims 3, 5, 6, 24-27, 42 and 44 above, and further in view of Schwartz et al (6,015,387). MacGregor fails to disclose the monitoring device as claimed. However, Schwartz teaches that such devices were known to the art at the time of the invention; see the abstract and figures. Therefore, it would have been obvious to include a monitoring device in the MacGregor device for the same reasons that Schwartz uses the same and in order to monitor the blood to see if the swirl flow desired is occurring.

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With regard to claims 14 and 15, the Schwartz sensor is electrically connected to the power supply and it electromagnetically transmits a signal to a remote monitor, which must have a power supply and recording means to function. This is necessary because the monitor performs a calculation and displays a result; see column 2, lines 25-36. The monitor of Schwartz also uses ultrasound to detect blood flow; see *supra*.

Response to Arguments

In response to the traversal of the rejections based upon MacGregor, the Examiner has modified the rejection such that the newly added language requiring at least partial helical shape imposition has been addressed.

Applicants traverse the Caro rejection by arguing that it is not for use within a vessel. The Examiner asserts that all the structural features of the intended use are clearly present in Caro and that the Caro device is capable of being used internally. For this reason, the Examiner asserts that the claim language is read on by Caro and fully anticipated thereby.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilio whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic
Primary Examiner
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